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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|--|-------------|----------------------|-------------------------|-----------------|
| 10/785,167 | 02/23/2004 | Dennis J. Slamon | G&C 30448.95-US-D1 | 8513 |
| 7590 07/13/2004 | | EXAMINER | | |
| Attn: William J. Wood | | | WINSTON, RANDALL O | |
| Gates & Cooper LLP Howard Hughes Center | | | ART UNIT | PAPER NUMBER |
| 6701 Center Drive West, Suite 1050 | | | 1654 | |
| Los Angeles, CA 90045 | | | DATE MAILED: 07/13/2004 | |

Please find below and/or attached an Office communication concerning this application or proceeding.

| r) ,, † | Application No. | Applicant(s) | | | | |
|---|---|--|--|--|--|--|
| | 10/785,167 | SLAMON ET AL. | | | | |
| Office Action Summary | Examiner | Art Unit | | | | |
| | Randall Winston | 1654 | | | | |
| The MAILING DATE of this communication appears on the cover sheet with the correspondence address | | | | | | |
| Period for Reply A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM | | | | | | |
| THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.1 after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a replent if NO period for reply is specified above, the maximum statutory period really reply received by the Office later than three months after the mailing earned patent term adjustment. See 37 CFR 1.704(b). | 36(a). In no event, however, may a reply be time within the statutory minimum of thirty (30) day will apply and will expire SIX (6) MONTHS from a cause the application to become ABANDONE | nely filed s will be considered timely. the mailing date of this communication. D (35 U.S.C. § 133). | | | | |
| Status | | | | | | |
| 1) Responsive to communication(s) filed on 23 F | <u>ebruary 2004</u> . | | | | | |
| 2a) ☐ This action is FINAL . 2b) ☑ This | his action is FINAL . 2b)⊠ This action is non-final. | | | | | |
| ,— | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | |
| Disposition of Claims | | | | | | |
| 4) Claim(s) <u>19-23</u> is/are pending in the application. | | | | | | |
| 4a) Of the above claim(s) is/are withdrawn from consideration. | | | | | | |
| 5)⊠ Claim(s) <u>20-23</u> is/are allowed. | | | | | | |
| 6)⊠ Claim(s) <u>19</u> is/are rejected. | | | | | | |
| 7) Claim(s) is/are objected to. | | | | | | |
| 8) Claim(s) are subject to restriction and/or election requirement. | | | | | | |
| Application Papers | | | | | | |
| 9) The specification is objected to by the Examiner. | | | | | | |
| 10) The drawing(s) filed on is/are: a) □ accepted or b) □ objected to by the Examiner. | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). | | | | | | |
| 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | |
| Priority under 35 U.S.C. § 119 | | | | | | |
| 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: | | | | | | |
| 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No | | | | | | |
| 3. Copies of the certified copies of the priority documents have been received in this National Stage | | | | | | |
| application from the International Bureau (PCT Rule 17.2(a)). | | | | | | |
| * See the attached detailed Office action for a list of the certified copies not received. | | | | | | |
| \cdot | | | | | | |
| Attachment(s) | | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | |
| 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail D | ate | | | | |
| 3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date (2) 24. 5) Notice of Informal Patent Application (PTO-152) 6) Other: | | | | | | |
| *************************************** | | | | | | |

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DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 19 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 19 is rendered vague and indefinite by the phrase "comprising frozen tissue embedding compound" (line 3). Based upon the overall teachings of the instant specification, this phrase is deemed incomplete because it does not reasonably define this essential element of the instantly disclosed invention - i.e., -- comprising a frozen tissue embedding compound having an array of holes disposed therein-- (see, e.g., MPEP 2172.01). It is strongly suggested that this phrase be expanded upon as indicated above so as to adequately define this essential limitation of the disclosed/claimed invention (as well as to help distinguish the claimed invention over the prior art - see, e.g., art rejection below).

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

⁽b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 19 is rejected under 35 U.S.C. 102(b) as being anticipated by Sharon (US 6,335,163).

Applicant claims a composition comprising at least one non-fixed biological sample embedded in a tissue microarray block, wherein the tissue micoarray block comprises frozen tissue embedding compound.

Sharon anticipates the claimed invention because Sharon teaches (see, e.g. column 21 lines 64-67) a non-fixed biological sample (i.e. tumor tissue) embedded into a frozen tissue embedding compound (i.e. polyvinyl alcohol and polyethylene glycol). Therefore, the reference anticipates the instant claim.

Claims 20-23 are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Randall Winston whose telephone number is 571-272-0972. The examiner can normally be reached on 8AM-5PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on 571-272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CHRISTOPHER R. TATE PRIMARY EXAMINER